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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,445	11/20/2003	Dirk Johannes Schaefer	24741-1532	6648
26633	7590	10/10/2006	EXAMINER	
HELLER EHRLICH WHITE & MCAULIFFE LLP 1717 RHODE ISLAND AVE, NW WASHINGTON, DC 20036-3001				NAFF, DAVID M
ART UNIT		PAPER NUMBER		
				1657

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/716,445	SCHAEFER ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 July 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,4-6,8,9,12,13 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,4-6,8,9,12,13 and 39 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 20 November 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 09/718,087.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/20/03</u> . | 6) <input type="checkbox"/> Other: _____ . |

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DETAILED ACTION

A response of 7/12/2006 to a restriction requirement of 6/16/06 elected with traverse Group I claims 1, 4-6, 8, 9, 12, 13 and 39, and canceled non-elected claims 28-35 and 38. Since the non-elected
5 claims have been canceled, the traverse is moot.

Claims examined on the merits are 1, 4-6, 8, 9, 12, 13 and 39, which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

10 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15 Claims 1, 4-6, 8, 9, 12, 13 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by claim 1 requiring a bone
20 substitute comprising components a), b) and c) since after component c) is formed this is the only component present. Components a) and b) form component c), and components a) and b) no longer exist as separate components after component c) is formed. The claim should require the bone substitute to comprise the setting matrix and specify
25 how the setting matrix is formed using components a) and b).

In c) of claim 1, "setting" is uncertain as to meaning and scope. The physical phenomena that constitutes "setting" is uncertain.

Claims 8 and 9 are unclear as to where in claim 1 the cells are present.

Claim 39 is confusing and unclear as to steps performed when using the device required for producing the bone substitute of claim

5 1. Claim 39 is product-by-process by requiring producing the bone substitute with the device, and in this case the claim must set forth clear, distinct and positive method steps. Claim 39 is further unclear as to the purpose of reciting in parenthesis "main channel" in b) and "subsidiary channels" in c), and whether these terms are to be 10 patentably limiting. It is suggested the terms in parenthesis be deleted, and in line 5 before "supply" insert --- main ---, and in line 7 cancel "other" and insert --- subsidiary ---. In line 9, the meaning of "the end of the subsidiary channel/the ends of the subsidiary channels" is unclear. This also applies to "subsidiary 15 channel/subsidiary channels" in line 11. There is not antecedent basis for "material" in line 10 and "the material stream" in line 11. Additionally, the relationship of the material to the bone substitute of claim 1 is unclear.

Claim Rejections - 35 USC § 103

20 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

25 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-6, 8, 9, 12, 13 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robey et al (5,914,121) in view of Costantino et al (document A08 on 1449 of 11/20/03) and Long et al (5,972,703).

The claims are drawn to a bone substitute containing a soft matrix formed by mixing osteoblasts or precursors thereof with a fibrinogen solution and a thrombin solution, and a setting matrix formed by mixing the soft matrix with a setting material comprising an aqueous solution of non-ceramic hydroxyapatite cement.

Robey et al disclose preparation of human bone *in vivo* by implanting a composition containing cells, ceramic powder containing hydroxyapatite and fibrin. For example, see claims 1-6.

Costantino et al disclose implanting a composition containing hydroxyapatite that sets *in vivo* for bone replacement.

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Long et al disclose (col 13, lines 30-35) combining fibrinogen and thrombin to produce a fibrin clot. The capacity of osteoblasts to produce proteolytic enzymes that lyse the clot is overcome by using epsilon-amino caproic acid (col 13, lines 36-40). Cells that 5 differentiate into osteoblasts are used to treat bone disorders. The cells can be cultivated in the presence of collagen, fibrinogen and fibrin (col 6, lines 40-45).

It would have been obvious to replace the ceramic powder of Robey et al with the hydroxyapatite composition suggested by Costantino et 10 al to obtain its setting function *in vivo*. Long et al would have suggested combining fibrinogen and thrombin to form fibrin by disclosing forming a fibrin clot by mixing fibrinogen and thrombin. Long et al would have further suggested adding aminocaproic acid as in claim 4 to prevent osteoblasts from lysing the clot. Since Long et al 15 use cells that differentiate into osteoblasts to form bone, it would have been obvious to include osteoblasts or precursors thereof in the composition of Robey et al.

Conclusion

Any inquiry concerning this communication or earlier 20 communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-

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0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN

15 9/29/06